

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12483



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12483

Jack Nickelson
602-379-4595 P02

COMPLAINT/INJURY REPORT

| | | | | | |
|---|--|---|--|--|--------------------------------------|
| COMPLAINT/INJURY REPORT | | | | 1. COMPLAINT NUMBER LOS-6749 | |
| | | | | 2. DATE OF COMPLAINT (MM/DD/YY) 07-30-97 | |
| 3. FORM OF COMPLAINT | | <input checked="" type="checkbox"/> (1) TELEPHONE <input type="checkbox"/> VISIT <input type="checkbox"/> LETTER | | 4. SOURCE OF COMPLAINT | |
| | | <input checked="" type="checkbox"/> (1) CONSUMER <input type="checkbox"/> GOVERNMENT <input type="checkbox"/> | | <input type="checkbox"/> TRADE SOURCE <input type="checkbox"/> OTHER <i>(Indicate in Remarks)</i> | |
| 5. COMPLAINT IDENTIFICATION | | a. NAME AND ADDRESS (Include Zip Code) | | | b. AREA CODE AND TELEPHONE WORK() |
| | | | | | |
| 6. COMPLAINT OR INJURY | | a. DESCRIPTION OF COMPLAINT/INJURY Complainant's wife has been taking the product for about one week one cap 3X a day before meals to lose weight. Collapsed at [redacted] and was treated and then air evac. to [redacted] is currently in I.C.U. with Neuro and heart problems currently on ventilator. <div style="text-align: right;">Cranial Hemorrhage [redacted]</div> | | | |
| | | DOES COMPLAINT EXPECT ADDITIONAL FDA CONTACT? <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES <i>(Explain in Remarks)</i> | | | |
| 7. INJURY OR ILLNESS RESULTED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES <i>(If "YES" complete items a through d)</i> | | a. EIB (HFC-161) NOTIFIED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES DATE 8-1-97 | | b. TYPE SYMPTOMS <input type="checkbox"/> (1) VOMITING <input type="checkbox"/> (2) NAUSEA <input type="checkbox"/> (3) DIARRHEA <input type="checkbox"/> (4) FEVER <input type="checkbox"/> (5) SKIN/EYE IRR. <input type="checkbox"/> (6) HEADACHE <input checked="" type="checkbox"/> (7) OTHER | |
| | | c. ATTENDING HEALTH PROFESSIONAL <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES (If "yes" give name, address, and phone no.) | | d. HOSPITALIZATION REQUIRED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES (If "yes" give name, address, and phone no. and dates) | |
| | | | | | |
| 8. PRODUCT AND LABELING | | a. BRAND NAME SHAPE-FAST PLUS | | | |
| | | b. PRODUCT NAME SHAPE-FAST PLUS | | | |
| | | c. NAME AND ADDRESS OF FIRM (Include Zip Code) SHAPE-FAST CONCEPTS INC 1638 S. REDWOOD ROAD SALT LAKE CITY, UT, 84115 <i>← Manufacturer. LR6</i> | | | |
| | | d. NAME AND LOCATION OF STORE WHERE PURCHASED Purchased from [redacted] | | | |
| | | e. SIZE AND PACKAGE TYPE 90 CAPSULE PLASTIC BOTTLE | | f. DATE PURCHASED within one week | |
| | | g. PACKAGE CODE/SERIAL NUMBER/ETC. P60787 EXP/USE BY DATE: | | h. AMT REMAINING 64 capsules | |
| | | i. DATE PURCHASED within one week | | j. PRODUCT USED (If "yes" enter date): <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES started using about 7-20-87 | |
| 9. MANUFACTURER/DISTRIBUTOR OF PRODUCT | | a. HOME DISTRICT DEN-DO b. C.F.NO. 1722000 c. NAME AND ADDRESS OF FIRM (Include Zip Code) SHAPE-FAST CONCEPTS INC 1638 S. REDWOOD ROAD SALT LAKE CITY, UT, 84115 <i>← Manufacturer. LR6</i> d. IMPORT PRODUCT <input checked="" type="checkbox"/> (1) NO <input type="checkbox"/> (2) YES | | | |
| 10. EVALUATION AND DISPOSITION | | a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX INJURY REACTION b. EVALUATION <input type="checkbox"/> (1) NOT AN FDA OBLIGATION <input type="checkbox"/> (2) OBLIGATION, NO VIOLATION <input checked="" type="checkbox"/> (3) FDA ACTION INDICATED <input type="checkbox"/> (4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE c. DISPOSITION <input checked="" type="checkbox"/> (1) IMMEDIATE FOLLOW-UP <input type="checkbox"/> (2) F/U NEXT EI <input type="checkbox"/> (3) CLOSED WITHOUT FURTHER INVESTIGATION <input type="checkbox"/> (4) REFERRED TO OTHER FEDERAL AGENCY <i>(Close file)</i> <input type="checkbox"/> (5) REFERRED TO STATE/LOCAL AGENCY <input type="checkbox"/> (6) REFERRED TO OTHER FDA-DEN-DO DISTRICT | | | |
| | | 11. PRODUCT CODE 64F0609 12. INFORMATION <input type="checkbox"/> HFN - 355 <i>(Biological)</i> <input type="checkbox"/> HFN - 730 <input type="checkbox"/> HFN - 333 <input type="checkbox"/> HFN - 236 COPIES TO: <input type="checkbox"/> HFC - 343 <input type="checkbox"/> HFC - 400 <input checked="" type="checkbox"/> HFC - 161 <input checked="" type="checkbox"/> DEN-DO, CFSAN | | | |

REMARKS

Detailed memorandum of investigation to follow with medical records

97 AUG -4 P4:37

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

100000

COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER
LOS-67492. DATE OF COMPLAINT (MM/DD/YY)
07-30-97

| | | | | | | | |
|--|--|---|--|--|--|--|--|
| 3. FORM OF COMPLAINT | | <input checked="" type="checkbox"/> (1) TELEPHONE <input type="checkbox"/> (2) LETTER <input type="checkbox"/> (3) VISIT | | 4. SOURCE OF COMPLAINT | | <input checked="" type="checkbox"/> (1) CONSUMER <input type="checkbox"/> (2) GOVERNMENT <input type="checkbox"/> (3) TRADE SOURCE <input type="checkbox"/> (4) OTHER (Indicate in Remarks) | |
| 5. COMPLAINT IDENTIFICATION | | a. NAME AND ADDRESS (Include Zip Code) [REDACTED] | | | | b. AREA CODE AND TELEPHONE HOME [REDACTED] WORK() | |
| 6. COMPLAINT OR INJURY | | a. DESCRIPTION OF COMPLAINT/INJURY Complainants wife has been taking the product for about one week one cap 3X a day before meals to lose weight. Collapsed at [REDACTED] and was treated and then air evac. to [REDACTED] Is currently in I.C>U> with Neuro and heart problems currently on ventilator. | | | | | |
| | | DOES COMPLAINT EXPECT ADDITIONAL FDA CONTACT? | | | | <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (Explain in Remarks) | |
| 7. INJURY OR ILLNESS RESULTED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES (If "YES" complete items a through d) | | a. EIB (HFC-161) NOTIFIED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES DATE 8-1-97 | | b. TYPE SYMPTOMS <input type="checkbox"/> (1) VOMITING <input type="checkbox"/> (2) NAUSEA <input type="checkbox"/> (3) DIARRHEA <input type="checkbox"/> (4) FEVER <input type="checkbox"/> (5) SKIN/EYE IRR. <input type="checkbox"/> (6) HEADACHE <input checked="" type="checkbox"/> (7) OTHER | | c. ATTENDING HEALTH PROFESSIONAL <input type="checkbox"/> (1) NO <input type="checkbox"/> (2) YES (If "yes" give name, address, and phone no.) [REDACTED] | |
| | | | | ONSET (HR.) — — — — — | | d. HOSPITALIZATION REQUIRED <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES (If "yes" give name, address, and phone no.) [REDACTED] | |
| 8. PRODUCT AND LABELING | | a. BRAND NAME SHAPE-FAST PLUS | | | | b. PRODUCT NAME SHAPERITE SHAPE-FAST PLUS | |
| | | c. SIZE AND PACKAGE TYPE 90 CAPSULE PLASTIC BOTTLE | | | | d. NAME AND LOCATION OF STORE WHERE PURCHASED Purchased from [REDACTED] | |
| | | e. PACKAGE CODE/SERIAL NUMBER/ETC. PS0787 EXP/USE BY DATE: | | f. DATE PURCHASED within one week | | g. PRODUCT USED (If "yes" enter date). <input type="checkbox"/> (1) NO <input checked="" type="checkbox"/> (2) YES started using about 7-20-97 | |
| | | | | | | h. AMT REMAINING 64 capsules | |
| 9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT | | a. HOME DISTRICT DEN-DO | | | | c. NAME AND ADDRESS OF FIRM (Include Zip Code) SHAPERITE CONCEPTS INC 1635 S. REDWOOD ROAD SALT LAKE CITY, UT. 84115 | |
| | | b. C.F.NO. 1722000 | | | | d. IMPORT PRODUCT <input checked="" type="checkbox"/> (1) NO <input type="checkbox"/> (2) YES | |
| 10. EVALUATION AND DISPOSITION | | a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION RX INJURY REACTION | | c. DISPOSITION <input checked="" type="checkbox"/> (1) IMMEDIATE FOLLOW-UP <input type="checkbox"/> (2) F/U NEXT EI <input type="checkbox"/> (3) CLOSED WITHOUT FURTHER INVESTIGATION <input type="checkbox"/> (4) REFERRED TO OTHER FEDERAL AGENCY (Closes file) <input type="checkbox"/> (5) REFERRED TO STATE/ LOCAL AGENCY <input checked="" type="checkbox"/> (6) REFERRED TO OTHER FDADEN-DO DISTRICT | | 11. PRODUCT CODE 54FCE09 | |
| | | b. EVALUATION <input type="checkbox"/> (1) NOT AN FDA OBLIGATION <input type="checkbox"/> (2) OBLIGATION, NO VIOLATION <input checked="" type="checkbox"/> (3) FDA ACTION INDICATED <input type="checkbox"/> (4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE | | | | 12. INFORMATION <input type="checkbox"/> HFN - 355 <input type="checkbox"/> HFN - 730 <input type="checkbox"/> HFN - 333 <input type="checkbox"/> HFV - 236 (Biologics) | |
| | | | | | | COPIES TO: <input type="checkbox"/> HFZ - 343 <input type="checkbox"/> HFZ - 400 <input checked="" type="checkbox"/> HFC - 161 <input checked="" type="checkbox"/> DEN-DO, CFSAN | |
| REMARKS Detailed memorandum of investigation to follow with medical records | | | | | | | |

000002

Adverse Reaction Questionnaire

Complaint Number: 105-6749Investigator: JOHN A. NICHOLSON

| Consumer Information | | |
|---|---|----------------|
| Date of Report: <u>07-30-97</u> MM/DD/YY | Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input checked="" type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC | |
| Name: [REDACTED] | Gender: <input checked="" type="checkbox"/> F <input type="checkbox"/> M | Age: <u>34</u> |
| Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown | | |
| Information on Adverse Reaction | | |
| Date of Adverse Reaction: <u>7-28-97</u> Previous Reaction to Product Type: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>HOME</u> | |
| The following information relates to the consumers' use of the product. Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): <u>SEE MEMO</u> How long did the symptoms last? Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.): <u>SEE MEMO</u> List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used <u>at the time</u> of the event: <u>SEE MEMO</u> Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable | | |
| Medical Information | | |
| Was a health care provider seen?: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <u>SEE ATTACHED MEMO OF INVESTIGATION</u> Give health care provider's name, address and telephone number: | | |
| Occupation of Health Care Provider: <input checked="" type="checkbox"/> MD <input checked="" type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input checked="" type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other (specify) <u>SEE ATTACHED MEMO</u> | | |
| What medical tests were performed and what were the results? <u>SEE ATTACHED MEMO OF INVESTIGATION</u> What was the medical diagnosis? What treatment(s) was given (e.g., drugs, other)? | | |
| Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | | |

Product Category

1. Adverse reaction to:

☐ Medical Food (under medical supervision) ☐ Infant Formula

☒ **Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands, garlic extract, fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)

☐ Other (traditional food) _____

Other Product Problems

2. ☐ Foreign Object (specify): _____

3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): SHAPE-FAST "TAKE ONE TO TWO CAPSULES DAILY 30 MINUTES BEFORE EACH MEAL"

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

EACH 400 MG CAPSULES CONTAINS "MILK HANDB CSMANHAIBED TO 13MG EPHEDRA ALKALOIDS, THE COLA ALKALOID 40 MG CAFFEINE THE " SEE ATTACHED COLLECTION REPORT [REDACTED]"

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐ Aspartame

☐ Monosodium Glutamate

☐ Sulfite

☒ Other EPHEDRA

☐ Unknown

☐ Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐ Yes ☒ No ☐ Unknown

Product Sample Available: ☐ Yes ☐ No ☐ Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ No

Life-Threatening: ☒ Yes ☐ No

Hospitalization: ☒ Yes ☐ No (if YES, indicate if initial or prolonged) CURRENTLY IN I.C.U. WILL BE FOR 2-3 WEEKS

Required intervention to prevent permanent impairment/damage: ☒ Yes ☐ No

Did the adverse reaction result in a congenital anomaly: ☐ Yes ☐ No UNKNOWN



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

LOS ANGELES DISTRICT OFFICE
INVESTIGATIONS BRANCH
19900 MACARTHUR BLVD. #300
IRVINE, CA. 92715

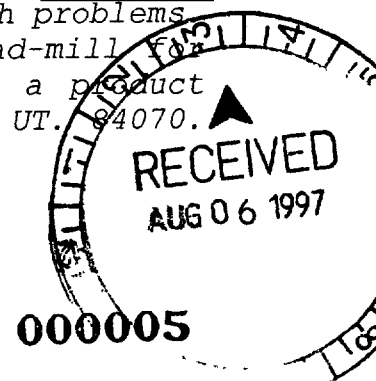
MEMORANDUM

DATE: August 1, 1997 Product Shape-Fast
 Mfr. ShapeRite
TO: James E. Kozick-LOS-DO Sandy, UT 84070
FROM: John A. Nicholson Patient [REDACTED]
 [REDACTED]
SUBJECT: Injury Investigation Ephedra Related Consumer Complaint
 LOS-6749 CFSAN PROJECT # 12483

On July 30, 1997 I received a telephone call from a [REDACTED] regarding his daughter being in intensive care due to the ingestion of a "Weight Loss" product that contains Ma Huang (Ephedra). The product is called "Shape-Fast" and is manufactured by ShapeRite of Sandy, UT. 84070. Mr. [REDACTED] indicated his daughter had been taking the Special Dietary for about one week prior to collapsing. According to [REDACTED] is in [REDACTED]

[REDACTED] Mr. [REDACTED] stated his daughter is on a ventilator and has neurological and cardiac problems brought on by the "Shape-Fast" product. I asked Mr. [REDACTED] why he thought the "Shape-Fast" product caused the problems. He stated both the neurological physician as well as the cardiac physician told him the ephedra in the product likely caused the injury. I made arrangements to meet with Mr. and Mrs. [REDACTED] and [REDACTED] husband [REDACTED] at [REDACTED] at 4:00 P.M. July 31st.

On July 31st I met with Mr. and Mrs. [REDACTED] and Mr. [REDACTED] to obtain more information into the injury to [REDACTED]. I was informed [REDACTED] was born on [REDACTED]. Ms. [REDACTED] is a healthy individual with no known health problems. [REDACTED] has been doing aerobics and working on a tread-mill for several years. About one week ago [REDACTED] purchased a product called "SHAPE-FAST" manufactured by ShapeRite, Sandy, UT. 84070.



The product was purchased from a [REDACTED]
[REDACTED] The "SHAPE-FAST" product contains Ma Huang which is labeled to be standardized to 15 mg. Ephedra alkaloids along with Cola and 40 mg. of caffeine. The label states to take one or two capsules 30 minutes before each meal. According to [REDACTED] his wife was taking one capsule before each meal and had been taking the capsules for about one week. (a count of the opened bottle showed 64 capsules present from the initial 90 capsules). On Monday July 28th [REDACTED] went to the [REDACTED] to take her aerobics class. While taking the class [REDACTED] collapsed and was transported by ambulance to [REDACTED]. After initial screening [REDACTED] was Air Evacuated to the [REDACTED] [REDACTED] is currently in the Intensive Care Unit at the [REDACTED] [REDACTED] has suffered damage to the brain, heart and CNS. [REDACTED] is currently on a ventilator to assist in her breathing. [REDACTED] is expected to be in the I.C.U. for at least three more weeks. The following doctors are involved in treating [REDACTED]: 1. Dr. [REDACTED] 2. Dr [REDACTED]; both of [REDACTED] 3.. Dr. [REDACTED] [REDACTED] cardiologist, [REDACTED]

On August 4, 1997 I went to the [REDACTED] to obtain a copy of the Accident Report that was made out on July 28, 1997 covering the incident with [REDACTED] Attached to this report is this Accident Report dated 7/28/97. This is attached as Exhibit A1.

On August 4, 1997 I went to [REDACTED] to obtain the medical records relating to their treatment of [REDACTED] Attached to this report are thirteen (13) pages of medical records. These records are identified as Exhibits B1/B13. These records indicate that [REDACTED] suffered a "subarachnoid hemorrhage" and was transferred by [REDACTED]

On August 5, 1997 I went to [REDACTED] to obtain medical records on [REDACTED] Attached to this report are the following medical records relating to [REDACTED]

Exhibits C1/C7-[REDACTED] Admitting diagnostic notes.

Exhibits D1/D29-Physician's Progress notes.

Exhibits E1/E13-Physician's Orders.

Exhibits F1/F13-Nursing Progress Notes.

Exhibits G1/G2-Radiology Monitoring Record.

Exhibits H1/H19-Medication Administration Records.

Exhibits J1/J21-Laboratory Records.

Exhibits K1/K6-Emergency Department Orders and Records.

Also attached to this report as exhibits are the following information relating to **"Shape-Fast"** and other **"ShapeRite"** products:

Exhibit L1/L2-ShapeRite Suggest Price List for ShapeRite products.

Exhibit M1/M2-National Dieter's Council information.


Exhibit N1/N2-ShapeRite Independent Distributor Product Information Bulletin. This booklet has the name and address of the [REDACTED]
[REDACTED]

Exhibit O-Shaperite Area Meeting Schedule for 1997.

Exhibit P-Suggested Product Combinations For The Shaperite Product Line.

Exhibit Q-ShapeRite Shapefast Plus Information booklet.

Exhibit R-Seven Day Cycle Diet.


John A. Nicholson, 144
[REDACTED] LOS-DO



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

LOS ANGELES DISTRICT OFFICE
INVESTIGATIONS BRANCH
19900 MACARTHUR BLVD. #300
IRVINE, CA. 92715

MEMORANDUM

DATE: August 18, 1997 **Product** Shape-Fast
REVISION OF 8-1-97 **Mfr.** ShapeRite
TO: James E. Kozick-LOS-DO **Sandy, UT** 84070

FROM: John A. Nicholson **Patient** [REDACTED]

SUBJECT: Injury Investigation Ephedra Related Consumer Complaint
LOS-6749 **CFSAN PROJECT # 12483**

On July 30, 1997 I received a telephone call from a [REDACTED] regarding his daughter being in intensive care due to the ingestion of a "Weight Loss" product that contains Ma Huang (Ephedra). The product is called "Shape-Fast" and is manufactured by ShapeRite of Sandy, UT. 84070. Mr. [REDACTED] indicated his daughter had been taking the Special Dietary for about one week prior to collapsing. According to [REDACTED] is in [REDACTED]

[REDACTED] stated his daughter is on a ventilator and has neurological and cardiac problems brought on by the "Shape-Fast" product. I asked Mr. [REDACTED] why he thought the "Shape-Fast" product caused the problems. He stated both the neurological physician as well as the cardiac physician told him the ephedra in the product likely caused the injury. I made arrangements to meet with Mr. and Mrs. [REDACTED] and [REDACTED] husband [REDACTED] at [REDACTED] at 4:00 P.M. July 31st.

On July 31st I met with Mr. and Mrs. [REDACTED] and Mr. [REDACTED] to obtain more information into the injury to [REDACTED]. I was informed [REDACTED] was born on [REDACTED]. Ms. [REDACTED] is a healthy individual with no known health problems. [REDACTED] has been doing aerobics and working on a tread-mill for several years. About one week ago [REDACTED] purchased a product called "SHAPE-FAST" manufactured by ShapeRite, Sandy, UT. 84070.

79 AUG 19 10:45

The product was purchased from a [REDACTED]
[REDACTED] The "SHAPE-FAST" product contains Ma Huang which is labeled to be standardized to 15 mg. Ephedra alkaloids along with Cola and 40 mg. of caffeine. The label states to take one or two capsules 30 minutes before each meal. According to [REDACTED] his wife was taking one capsule before each meal and had been taking the capsules for about one week. (a count of the opened bottle showed 64 capsules present from the initial 90 capsules). On Monday July 28th [REDACTED] went to the [REDACTED] to take her aerobics class. While taking the class [REDACTED] collapsed and was transported by ambulance to [REDACTED]. After initial screening [REDACTED] was Air Evacuated to the [REDACTED] is currently in the Intensive Care Unit at the [REDACTED] [REDACTED] has suffered damage to the brain, heart and CNS. [REDACTED] is currently on a ventilator to assist in her breathing. [REDACTED] is expected to be in the I.C.U. for at least three more weeks. The following doctors are involved in treating [REDACTED] 1. Dr. [REDACTED] 2. Dr. [REDACTED] both of [REDACTED] 3.. Dr. [REDACTED] cardiologist, [REDACTED]

On July 31, 1997 I collected the remaining portion of the "Shape-Fast" capsules that [REDACTED] had been consuming. The capsules were collected as 97-757-340. The sample was submitted to SEA-DO laboratory to the attention of Tom Savage.

On August 4, 1997 I went to the [REDACTED] to obtain a copy of the Accident Report that was made out on July 28, 1997 covering the incident with [REDACTED]. Attached to this report is this Accident Report dated 7/28/97. This is attached as Exhibit A1.

On August 4, 1997 I went to [REDACTED] to obtain the medical records relating to their treatment of [REDACTED]. Attached to this report are thirteen (13) pages of medical records. These records are identified as Exhibits B1/B13. These records indicate that [REDACTED] suffered a "subarachnoid hemorrhage" and was transferred by [REDACTED]
[REDACTED]

I was unable to copy the label from the bottle of "Shape-Fast" as was SEA-DO. On August 5, 1997 SEA-DO laboratory submitted a "verified" copy of the product labeling which is attached.

On August 5, 1997 I went to [REDACTED]
[REDACTED] to obtain medical records on [REDACTED]
[REDACTED] Attached to this report are the following medical
records relating to [REDACTED]

Exhibits C1/C7 [REDACTED] Admitting diagnostic
notes.

Exhibits D1/D29-Physician's Progress notes.

Exhibits E1/E13-Physician's Orders.

Exhibits F1/F13-Nursing Progress Notes.

Exhibits G1/G2-Radiology Monitoring Record.

Exhibits H1/H19-Medication Administration Records.

Exhibits J1/J21-Laboratory Records.

Exhibits K1/K6-Emergency Department Orders and Records.

On August 11, 1997 I contacted Dr. [REDACTED] the cardiologist
working on [REDACTED] regarding possible implication of the
"Shape-Fast" product containing Ephedra. Dr. [REDACTED]
informed me that the Ephedra was very likely responsible for
bringing on the hypertension and resulting injuries incurred by Ms.
[REDACTED]

On August 15, 1997 Dr. Lisa Ginn of O.S.N.-CFSAN contacted me and
asked for additional dictated diagnosis and assessment records of
the physicians treating [REDACTED] These are attached as
exhibits S through U.

Also attached to this report as exhibits are the following
information relating to "Shape-Fast" and other "ShapeRite"
products:

Exhibit L1/L2-ShapeRite Suggest Price List for ShapeRite
products.

Exhibit M1/M2-National Dieter's Council information.

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[REDACTED]

Exhibit O-ShapeRite Area Meeting Schedule for 1997.

Exhibit P-Suggested Product Combinations For The Shaperite Product Line.

Exhibit Q-ShapeRite Shapefast Plus Information booklet.

Exhibit R-Seven Day Cycle Diet.

Exhibit S1/S2-[REDACTED] History & Physical Report dated 7-28-97. Dr. [REDACTED] Dr. [REDACTED]

Exhibit T1/T2-[REDACTED] Assessment/Consultation dated 7-28-97. Dr. [REDACTED]

Exhibit U1/U2-[REDACTED] Assessment/Consultation dated 7-29-97 Dr. [REDACTED]


John A. Nicholson, 144
[REDACTED] LOS-DO

CC: J. Rowe HFC-161
Dr. L. Ginn-OSN, CFSAN HFS-451
H. Carrillo LOS-DO
HFS-636 Project 12483